

CLAIMS

What is claimed is:

Claim 1. A diagnostic marker including a binding protein indicative of a loss of self tolerance of Schwann cell protein comprising:
an autoantibody or an immunologically detectable fragment thereof capable of recognizing an epitope of Schwann cell breakdown.

Claim 2. The diagnostic marker of claim 1 wherein:
said autoantibody is capable of recognizing an epitope of glial fibrillary acidic protein.

Claim 3. A diagnostic assay test kit for diagnosing the existence, pre-disposition or risk of developing an autoimmune disease in a patient said kit comprising:

a front panel comprising a sample window and a display window, the sample window to receive a bodily fluid from said patient;

a back panel; and a dry chemistry membrane affixed between the front and back panels positioned for display in at least the display window,

wherein, said membrane comprises:

1 a sample region and a control region, said sample region
2 positioned to receive the sample from the sample window; and
3 at least one antibody pair located at a discrete
4 location along said membrane between the sample region and
5 the control region, each of said antibody pairs comprising an
6 antibody reagent member and an immobilized capture antibody
7 member, each capture antibody member being located on said
8 membrane closer to the control region than the corresponding
9 antibody reagent member, each antibody pair having a
10 measurable or observable moiety labeled or chemically bonded
11 to the antibody reagent member of each said antibody pairs,
12 the antibody pairs being monoclonal or polyclonal and
13 comprising:

14 at least one antibody pair that specifically binds to a
15 marker of Schwann cell injury or cell death,

16 such that upon adding sample to the sample window,
17 analytes present in the sample and complementary to the
18 antibody pairs will migrate toward the control region,
19 binding to the antibody pair each of said analytes, producing
20 a color change proportional to the each of analyte present
21 from which a diagnosis of autoimmune disease is made.

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1 Claim 4. The diagnostic assay test kit of claim 3
2 wherein:

3 said autoimmune disease is selected from the group
4 consisting of diabetes, prediabetes and multiple sclerosis
5 and pre-multiple sclerosis.
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7 Claim 5. The diagnostic assay test kit of claim 3
8 wherein:

9 said marker of Schwann cell injury or cell death is
10 selected from the group consisting of glial fibrillary acidic
11 protein (GFAP), S100 and GAD65.
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13 Claim 6. The diagnostic assay test kit of claim 3
14 wherein:

15 said body fluid is selected from the group consisting of
16 blood, blood components, urine, saliva, lymph and
17 cerebrospinal fluid.
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19 Claim 7. A process for detection of Schwann cell
20 autoantibody as a marker for the presence, predisposition or
21 risk for development of an autoimmune disease comprising the
22 steps of:

23 drawing a sample of body fluid from a patient,
24 depositing the sample in a sample window of a diagnostic
25 test kit, said test kit comprising

1 a front panel comprising a sample window and a display
2 window;
3 a back panel; and
4 a dry chemistry membrane affixed between the front and
5 back panels positioned for display in at least the display
6 window, wherein said membrane comprises:
7 a sample region, and a control region, said sample
8 region positioned to receive the sample from the sample
9 window; and
10 at least one antibody pair located at discrete locations
11 along said membrane between the sample region and the control
12 region, each said antibody pair comprising an antibody
13 reagent member and an immobilized capture antibody member,
14 each capture antibody member being located on said membrane
15 closer to the control region than the corresponding antibody
16 reagent member, each antibody pair having a measurable or
17 observable moiety labeled or chemically bonded to the
18 antibody reagent member of each said antibody pair,
19 each said at least one antibody pair being monoclonal or
20 polyclonal and comprising:
21 at least one pair that specifically binds to a marker of
22 Schwann cell injury or cell death,
23 such that upon adding sample to the sample window,
24 analytes present in the sample and complementary to the
25 antibody pairs will migrate toward the control region,
26 binding to the antibody pair each of said analytes, producing

1 a color change proportional to each concentration of analyte
2 present, and

3 visualizing or measuring the moiety and diagnosing the
4 presence of an autoimmune disease.

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6 Claim 8. The process of claim 7 wherein said autoimmune
7 disease is selected from the group consisting of Type 1
8 diabetes, prediabetes, pre-multiple sclerosis and multiple
9 sclerosis.

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11 Claim 9. The process of claim 7 wherein:
12 said Schwann cell autoantibody is autoreactive with
13 Glial Fibrillary Acidic Protein (GFAP).

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15 Claim 10. The process of claim 7 wherein:
16 said Schwann cell autoantibody is autoreactive with GAD-65.

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18 Claim 11. A diagnostic assay kit for autoimmune disease
19 comprising:

20 at least one immunologically reactive marker having an
21 affinity for glial fibrillary acidic protein (GFAP), and
22 a means for determining binding between each of said
23 respective markers and each of said respective antibodies.

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25 Claim 12. Anti-GFAP IgG useful as a predictive marker of
26 autoimmune disease.

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2 Claim 13. A process for prediabetes screening and
3 staging comprising:

4 drawing a sample of body fluid from a patient,
5 contacting said sample with a diagnostically effective
6 amount of an anti-GFAP IgG useful as a predictive marker of
7 Type 1 diabetes, and
8 determining binding between said anti-GFAP IgG and
9 immunologically detectable fragments contained within said
10 sample.

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12 Claim 14. A process for interfering with the course,
13 progression and/or manifestation of an autoimmune disease in
14 a mammal comprising:

15 interfering with the disease process by administering to
16 said mammal a therapeutically effective modality, said
17 modality having a degree of immunological reactivity
18 sufficient to modify the pathogenicity of lymphocytes
19 specific in instigating loss of self tolerance of Schwann
20 cell protein,

21 whereby said administration is effective to alter the
22 course, progression and/or manifestation of said
23 disease.

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25 Claim 15. The process of claim 14 wherein said
26 autoimmune disease is selected from the group consisting of

1 diabetes, prediabetes, multiple sclerosis and pre-multiple
2 sclerosis.

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4 Claim 16. A process for identifying a therapeutic moiety
5 useful in treating diabetes, prediabetes, multiple sclerosis
6 and pre-multiple sclerosis comprising:

7 recognizing at least one moiety for which a direct
8 therapeutic value is predicted,

9 contacting said moiety with at least one biopolymer
10 marker indicative or predictive of a disease state selected
11 from the group consisting of diabetes, prediabetes, multiple
12 sclerosis and pre-multiple sclerosis, and

13 determining modulation of said at least one biopolymer
14 marker attributable to said therapeutic moiety;

15 whereby a product having a confirmed therapeutic value
16 is identified.

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18 Claim 17. The product identified via the process of
19 claim 16.

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21 Claim 18. A process for identifying a therapeutic moiety
22 useful in treating diabetes, prediabetes, multiple sclerosis
23 and pre-multiple sclerosis comprising:

24 recognizing at least one moiety for which an indirect
25 therapeutic value is predicted,

1 contacting said moiety with at least one biopolymer
2 marker indicative or predictive of a disease state selected
3 from the group consisting of diabetes, prediabetes, multiple
4 sclerosis and pre-multiple sclerosis, and
5 determining modulation of said at least one biopolymer
6 marker attributable to said therapeutic moiety;
7 whereby a product having a confirmed therapeutic value
8 is identified.

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10 Claim 19. The product identified via the process of
11 claim 18.

12 Claim 20. The process for interfering with the course,
13 progression and/or manifestation of an autoimmune disease in
14 a mammal in accordance with claim 14 wherein:
15 said therapeutically effective modality is an
16 immunotherapeutic moiety defined as an effective analogue for
17 a major epitope peptide in GFAP which pathogenicity of key
18 lymphocytes which are specific for a native epitope in GFAP,
19 said analogue having structural similarity but not identity
20 in peptide sequencing able to be recognized by T-cells
21 spontaneously arising and targeting an endogeneous self
22 epitope,

23 whereby an altered T-cell activation occurs which leads
24 to T-cell anergy or death.